



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,901	09/27/2001	Mark S. Roby	2788	3223

7590 11/16/2004

Chief Patent Counsel
United States Surgical
Division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

CAMERON, ERMA C

ART UNIT	PAPER NUMBER
----------	--------------

1762

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,901

Applicant(s)

ROBY ET AL.

Examiner

Erma Cameron

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Non-Compliant Amendment

1. The claims in the 6/21/2004 Response after Final Rejection are non-compliant: canceled claims 16-29 contain text, which is not proper. However, the claims have been entered.

Applicant should correct this in the next response.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 5-7, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey (5,911,711).

Pelkey teaches a method of coating a needle, which inherently has a surface, by applying a coating mixture to the surface of the needle. The coating mixture of Pelkey contains a polydialkylsiloxane, with a viscosity of 12,500 cs (col. 3, line 15) and one other siliconization material (col. 3, line 13), known by MDX 4-4159. The mixture of Pelkey is then cured (col. 3, line 45), as required by claim 1.

Based on the density of polydimethylsiloxane, it appears that the viscosity of 12,500 cs would meet the limitation of "at least about 10,000 cp", as required by Applicant. Additionally,

Art Unit: 1762

because the polydialkylsiloxane is polydimethylsiloxane, as required later in claim 4, and the siliconization material is the same as one described in the instant specification and in later dependent claims, the molecular weights will inherently provide a viscosity of the coating mixture of at least 10,000 cp, as required by Applicant.

While Pelkey's coating method is specifically directed to "hypodermic needles", Examiner notes that hypodermic needles may be used during the course of surgery. Additionally, it is Examiner's position that Pelkey's method of lubricating hypodermic needles to decrease the penetration force would also be useful in needles used in surgery. It would have been obvious to one of ordinary skill in the art to use Pelkey's method of lubricating hypodermic needles on surgical needles to decrease the force necessary to pierce flesh during surgery, rendering surgery less tiring for the surgeon and less painful for the patient.

Regarding claim 2, Pelkey teaches the use of the polydialkylsiloxane in a solvent and the siliconization material (MDX) in a solvent (col. 3, lines 12 and 17).

Regarding claims 5-7, the siliconization material of Pelkey, MDX 4-4159, is dimethoxysilyldimethylaminopropyl silicone and another dimethylsiloxane copolymerizable therewith, as defined by Pelkey and as known in the art. These compounds qualify as an "aminoalkyl siloxane" and a "polydimethylsiloxane having amino and alkoxy functional groups". The siliconization material of Pelkey is supplied in a mixture of solvents, including isopropyl alcohol (col. 3, line 13).

Needles are dipped, as required by claim 9 (col. 3, line 21).

Pelkey teaches that, after the mixture above is applied to the needles, they are stored to become at least partially cured and that the cure may be allowed to occur under ambient

Art Unit: 1762

conditions, but that the rate of cure may be accelerated by oven warming until sufficiently cured (col. 3, lines 29 and 45-55). This two-step curing method involving a first-step of storing, which would evaporate the solvent (col. 4, line 7), and a second step of oven curing reads on Applicant's two-step curing method outlined in claims 10-13.

In the first step of storing, Pelkey does not specify conditions. In the absence of a showing of criticality and in light of Pelkey's disclosure of ambient conditions being suitable for the coated substrates, it is Examiner's position that it would have been obvious to an ordinary artisan to store Pelkey's coated needles under ambient conditions, which fall within Applicant's temperature and relative humidity ranges claimed in claims 10-13. Regarding the length of time useful for this storing step which partially cures the coating in the method of Pelkey, it is Examiner's position that selection of an optimal time would have been within the skill of an ordinary artisan depending on the amount of cure desired prior to the oven stoving stage of the curing operation.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the stoving operation, Pelkey teaches the use of temperature up to 100 °C or higher unless the hub is thermoplastic (col. 3, lines 45-55). Since surgical needles do not have hubs, this teaching allows temperatures of over 100 °C, overlapping the ranges claimed by Applicant.

Art Unit: 1762

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Pelkey's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Pelkey teaches that the oven curing occurs until the coating is sufficiently cured, but does not teach a time for such sufficient curing. However, it is Examiner's position that optimizing cure time for a given temperature would have been within the skill of an ordinary artisan desiring to achieve a "sufficient curing" for those reasons outlined above.

The selection of heating times and temperatures would have been selected and optimized by one of ordinary skill in the art for those reasons outlined above, regarding claim 14.

The applicant has argued in the 6/21 response that the coating would not have the claimed viscosity. However, it would have been obvious to one of ordinary skill in the art to have optimized viscosity through no more than routine experimentation as viscosity is known to be an important and controllable parameter in coating.

Furthermore, applicant argues that even though one of the coating materials has a viscosity of 12,500, that there is no evidence that the viscosity of the "coating mixture" will be greater than 10,000.

Examiner disagrees. Examiner maintains the inherency rejection of this particular limitation. Applicant requires a "polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000". Examiner maintains that since Applicant later requires the use of, specifically, polydimethylsiloxane in a dependent claim

Art Unit: 1762

and that Pelkey teaches the use of the same, that this compound inherently has a molecular weight necessary to provide the desired viscosity. Clearly, a viscosity of 12,500 of a first component of a mixture has the *ability* to provide a coating mixture with a viscosity of 10,000 or more, based on the selection of the other mixture components. Most importantly, the mixture of Applicant requires polydimethylsiloxane and a siliconization material. The siliconization material of Pelkey (MDX 4-4159) and the polydialkylsiloxane of Pelkey (polydimethylsiloxane) are the same as those claimed by Applicant and as outlined by Applicant in his instant specification (p. 5 and p. 7). Therefore, the mixture of Pelkey would have the same properties as Applicant's.

Applicant argues that Pelkey teaches hypodermic needles, not surgical needles and that there is a difference between their uses.

Examiner notes that the limitation for a surgical needle is merely the intended use of the product. The eventual use of the needle is not germane to the issue of patentability. Additionally, Examiner maintains that the needles of Pelkey *could* very well be used during the course of surgery and both types of needles would benefit from a coating that decreases the penetration or drag force of insertion. Merely because the needles of Pelkey *may* not be required to remain lubricious for multiple passages through the skin/tissue, they would inherently be capable of doing so because the same types of coatings are supplied to the same types of substrate materials.

Applicant argues that the two-step curing operation and related process parameters of his invention, as outlined by dependent claims, is not suggested by Pelkey.

Examiner notes, as is taught in the previous office action, that Pelkey teaches coating the mixture onto the needles under ambient conditions, uprighting them, and then storing them for a time sufficient to achieve a partial cure. Because storing occurs after ambient coating, it is immediately envisioned by one of ordinary skill in the art that ambient conditions would persist while storing in the upright state to allow the partial cure to occur. Without a teaching to the contrary, such as is the case in the second stage of curing, in which an oven is used, one of ordinary skill in the art, upon review of the reference as a whole, would have envisioned the partial cure to occur at the ambient conditions discussed in col. 3, line 22. Because ambient conditions lie within the range of temperature, humidity, etc. claimed by Applicant, the reference meets said limitations. Then, Pelkey teaches, to achieve a full cure oven heating is used in which temperatures above 100 C may be used so long as the needle does not contain thermoplastic parts, which Applicant's does not. Therefore, this heating temperature overlaps that of Applicant as well, as outlined in the previous office action. While the time frames for the ambient partial cure and heated full cure are not specifically disclosed by Pelkey Examiner maintains that selection of a time for curing would have been obvious to one of ordinary skill in the art based on the chemicals being cured and the temperature at which curing is conducted. Because the chemicals to be cured are the same in Pelkey as those required by Applicant and the temperatures overlap, selection of the time necessary to achieve a cure would have been within the skill of an ordinary artisan.

Therefore Examiner maintains Pelkey teaches a two-step curing method involving a first-step of storing for a partial cure and a second step of oven curing, as required by Applicant.

4. Claims 3-4, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey in view of Mathisen et al. (5,456,948).

Pelkey teaches that which is disclosed above regarding the application of a polydimethylsiloxane and siliconization material in solvents. Particularly, Pelkey teaches the application of polydialkylsiloxane in a substantially non-polar volatile and inert solvent (col. 3, line 29), but fails to specifically teach the use of hexane.

Mathisen teaches a method of lubricating medical articles, such as surgical needles, with a solution of polydialkylsiloxane in hexane (col. 3, line 10, col. 4, line 14, col. 4, line 42; examples). Hexane is a hydrocarbon of 5-10 carbon atoms, as required by claim 3. It is also an example of a substantially nonpolar, volatile, inert solvent, as called for by Pelkey. Since Pelkey teaches the use of a nonpolar, volatile, inert solvent for use with polydialkylsiloxane for coating needles and Mathisen teaches the use of hexane as such a solvent for polydialkylsiloxane, Mathisen would have reasonably suggested the use of hexane in the method of Pelkey. It would have been obvious to one of ordinary skill in the art to use the teachings of Mathisen in the method of Pelkey with the expectation of successful results since Mathisen teaches the suitability of hexane with polydialkylsiloxane for coating needles.

Pelkey teaches that the polydialkylsiloxane of his invention is polydimethylsiloxane, as also required by claim 4 (col. 3, line 15).

The limitations of claim 8 are discussed in regards to claim 3-4 in this rejection and claims 5-7 of the Pelkey rejection, taken together.

Regarding claim 15, Pelkey teaches the use of the first siloxane and the siliconization material (MDX) in a ratio of 2:4, or 1:2, lying within the range claimed by Applicant (col. 3, lines 11 and 14).

Applicant argues that Mathisen fails to teach the deficiencies of Pelkey, said deficiencies being noted above.

Examiner notes that Mathisen was not cited to teach a 2-step curing operation or a method of coating needles, but merely to provide a teaching for the use of hexane as a suitable solvent for polydialkylsiloxane.

5. Claims 1-2, 9 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 627474.

‘474 teaches applying a composition of aminoalkyl siloxane, dimethyl cyclosiloxane, (these being part of MDX Fluid 4-4159, one of the commercial solutions used by applicant), and polydimethylsiloxane in water as a solvent to surgical needles by dipping (2:42-3:3; 5:2-4), and then curing (5:13-20).

‘474 does not teach the viscosity of the composition, but it would have been obvious to one of ordinary skill in the art to have optimized viscosity through no more than routine experimentation as viscosity is known to be an important and controllable parameter in coating.


Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron
Primary Examiner
Art Unit 1762

November 10, 2004